IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SCIREX CORPORATION : CIVIL ACTION

:

V.

:

FEDERAL INSURANCE COMPANY : NO. 00-1129

ADJUDICATION

Fullam, Sr. J. November , 2001

This case, involving an insurance coverage dispute, has been tried non-jury. The trial record consists of a lengthy "Stipulation of Facts" and voluminous agreed-upon exhibits. The Stipulation of Facts is incorporated herein by reference.

Although there is no dispute as to the facts, the inferences to be drawn from those facts, and the legal conclusions they justify, are very much in dispute, and will be discussed in this adjudication.

Plaintiff Scirex Corporation is a national concern which, at various locations, handles the clinical testing of proposed new drugs for pharmaceutical companies. The events giving rise to this lawsuit occurred at plaintiff's clinic in West Hartford, Connecticut, and involved four separate clinical trials designed to test the efficacy and safety of experimental drugs for the relief of pain following oral surgery. Two of these studies were conducted for a firm named Algos, one was conducted for Forest Labs, and one for the R. W. Johnson firm.

Plaintiff sustained very substantial losses because, as a result of employee misconduct, all four of the clinical trials had to be scrapped.

The defendant Federal Insurance Company had issued to plaintiff a succession of "crime insurance" policies providing coverage for "blanket employee dishonesty," and the ultimate issue to be decided is whether the losses sustained by plaintiff are covered by these policies.

The applicable policy form remained the same in all pertinent respects during each of the years involved in this case, hence all of the sequential policies will be discussed herein as if they constituted a single insurance policy. The policy obligates the defendant to:

"pay for direct loss caused by any fraudulent or dishonest acts committed by [Scirex's] employees, whether acting alone or in collusion with others, not to exceed the Limit of Insurance for Blanket Employee Dishonesty shown in the Declarations."

The policy further provides that "the loss must occur to money, securities or other property."

The parties disagree as to whether plaintiff's loss was caused by "fraudulent or dishonest acts"; whether the loss was "direct"; and whether the loss occurred "to money, securities or other property." The parties also disagree as to the correct application of the "limits of insurance," set forth in the policy in the following language:

"The most we will pay for any loss under Blanket Employee Dishonesty for any loss caused by any employee whether acting alone or in collusion with others, either resulting from a single act or any number of acts, regardless of when those acts occurred during the period of this insurance or prior insurance, is the amount of loss, not to exceed the Limit of Insurance for Blanket Employee Dishonesty shown in the Declarations...

"All losses resulting from an actual or attempted fraudulent or dishonest act or series of related acts at the premises...whether committed by one or more persons will be deemed to be one occurrence or event."

Each of these issues will now be addressed.

I. Fraudulent or Dishonest Acts

Proper resolution of the coverage issue requires an understanding of the clinical studies being performed by plaintiff. Each study was governed by a "protocol" issued by the drug manufacturer, governing the administration of the clinical tests. As mentioned previously, each of the drugs being tested was to be administered in connection with dental surgery performed, at the plaintiff's clinic, by a dental surgeon.

Nurses employed at the clinic were expected to observe each patient for a period of eight hours after the surgery, including periodic checks of body temperature and the amount of pain being suffered by the patient (as specified by the patient on a scale of 1-to-10), at stated intervals, and to note whether the patient

suffered adverse reactions from the drug (e.g., headaches, nausea, etc.).

The protocols contemplated that each patient would remain at the clinic for eight hours post-surgery. However, some of the patients suffered such severe pain and discomfort that it became apparent, or at least likely, that the drug being tested was not working. In such cases, the nurses were expected to administer alternative analgesic medications already known to be effective. Such patients were characterized as having been "rescued." The fact that such rescue had become necessary was useful in the clinical trials, but the nurses' observations of the patients after the rescue provided little or no information which was useful to the clinical study, although it was, of course, desirable to attend to the welfare of the patients.

The dental surgery involved removal of impacted wisdom teeth, in patients of a specified age group. Several patients would be treated in the course of a day, at intervals, each on a slightly different schedule. The nurse in charge of patient follow-up was Mary Ellen Conforto. She, or other nurses under her supervision, prepared a schedule for each patient commencing immediately after completion of the oral surgery, and specifying the times at which each observation was to be made, and the projected time of discharge at the end of the eight-hour period. Adverse reactions or other untoward events were to be noted on

this schedule.

The first of the four clinical studies involved in this case began on September 3, 1996 and was completed on February 13, 1997, and involved an analgesic "Morphidex" manufactured by Algos. The protocol for that study specified that each patient was to remain at the clinic for the full eight hours after surgery, but as the study progressed it was agreed by Algos that "rescued" patients need not remain at the clinic after the rescue medication was administered, but would be subject to follow-up telephone calls to make sure everything was all right.

A second study for Algos, involving the drug

Hydrocodex, began on April 10, 1997 and extended through October

13, 1997. Concurrently, a study of the drug Oxycodone on behalf

of Forest Labs began on April 2, 1997 and ended on September 24,

1997. The final study involved in this case involved the drug

Tram-Anag-011 and was performed for the R. W. Johnson Company,

beginning November 20, 1997 and ending on April 2, 1998. In all

three of the latter studies, the nursing staff, at Ms. Conforto's

direction, allowed "rescued" patients to leave the clinic before

the completion of the eight-hour period, and, in many instances

also permitted patients who had not been administered alternative

medication to go home before the eight-hour observation period

was over; in such cases, the nurses obtained the required follow
up information by telephone. The fact that patients left the

clinic early was not always reflected in the nurses' records they simply allowed the departure time stated on the original
schedule to remain unchanged.

The foregoing irregularities were first disclosed when a disgruntled former employee wrote a letter to plaintiff's management, recounting a laundry-list of complaints she had about Ms. Conforto. As a result of this letter, plaintiff caused audits to be performed on all four clinical studies, reported the findings to the respective drug manufacturers, and, eventually, determined that all four studies were useless. Payments received on account were refunded and, in some cases, the studies were redone without additional charge.

There can be no doubt that the failure of the nurses to comply with the requirements of the various protocols - or at least the last three protocols - constituted a serious breach of their employment responsibilities. By failing to note accurately the time when each non-rescued patient actually left the clinic - or, perhaps more accurately, by failing to note on the previously-drafted schedule that the stated departure time was incorrect - the nurses plainly undermined the validity of the clinical studies. But it does not follow that their actions can properly be characterized as "fraudulent or dishonest acts." The defendant did not issue a performance bond, but rather a "crime insurance" policy covering "blanket employee dishonesty."

Plaintiff seeks to characterize the nurses' conduct as "a knowing violation of the requirements of the protocols, with intentional misrepresentation on patient records to hide that violation." But the evidence as a whole makes clear that Ms. Conforto and the other nurses honestly believed that they were substantially complying with the requirements of the protocols. In their view, they were adequately following up each patient for the required eight hours and, unless unusual after-effects were noted, there was no real need to keep the patients at the clinic when they wanted to go home early. Ms. Conforto has had a great deal of experience in these matters, and is firmly convinced that it is standard nursing practice to set up schedules in advance, and to use such schedules as the basis for "nurses notes" of treatment. Obviously, her attitude is at odds with the meticulous requirements of the clinical studies involved in this case, but I am persuaded that the record reflects, at most, a stubborn belief that the nurses were right and that the drug companies were imposing unreasonable and unnecessary requirements.

The policy does not provide a definition of the terms "fraudulent or dishonest acts," hence it must be assumed that the parties intended those words to have their normal meanings. Both "fraudulent" and "dishonest" focus upon the intent of the actor, and connote intentional conduct perceived by the actor as

wrongful. Neither Ms. Conforto nor any of the other nurses can properly be characterized as having acted with that kind of dishonest intent. They gained no personal benefit from their actions, except perhaps a slight reduction in paperwork, yielding an earlier end of their workday, but such shirking and cornercutting does not fit comfortably within any reasonable understanding of fraud or dishonesty.

It is not without significance that, when the irregularities became known, Ms. Conforto was accused of "negligence," and, upset by that characterization, she resigned. The other nurses either resigned or were discharged. But no criminal charges were filed, or sought; and Ms. Conforto soon obtained employment with another firm, doing substantially the same kind of work she did for plaintiff; in her quest for employment, she was aided by letters of reference supplied by her superiors and co-workers at plaintiff's clinic.

In short, I have concluded that the losses sustained by plaintiff, for which recovery is sought in this action, were not the result of "fraudulent or dishonest acts," and are not covered by the insurance policy issued by the defendant.

Although this finding, standing alone, is dispositive, in the interest of completeness and in aid of any post-trial proceedings which may ensue, it is appropriate to deal with the

other issues raised by the parties.

II. "Direct" Loss to "Money, Securities or Other Property."

It should be noted at the outset that a literal interpretation of some of the policy language is difficult to square with a literal interpretation of other parts of the policy. Everyone agrees, for example, that embezzlement by an employee would be covered, yet it would seem that, actually, that would be a loss of money, rather than "to" money. In order to reconcile the coverage language in subparagraph (a), page three of the policy providing coverage for "direct loss caused by any fraudulent or dishonest acts" with the language of paragraph (b) on the same page, that "the loss must occur to money, securities or other property," it seems reasonable to interpret these provisions as including coverage both for loss of money or property, and loss attributable to damage to property, when in either case, the loss is the direct result of employee dishonesty.

Obviously, the nurses did not misappropriate money, or damage money. But the defendant's Claims Department has always conceded that the clinical studies involved in this case can properly be regarded as constituting "property" within the meaning of the policy and, in any event, ambiguities in that regard should be resolved in favor of plaintiff.

The issue then becomes, did the actions of the nurses directly cause the loss - i.e., the damage to the clinical studies. I conclude that they did - i.e., that this was a "direct loss." But, as discussed in the following section, that finding does not end the matter.

III. Calculating Plaintiff's Damages

As noted above, it is only by characterizing the clinical studies as "property" that a valid argument for coverage can be maintained. But treating the studies as "property," and the "loss to" such property as including damage, gives rise to additional problems.

At page 7 of the policy, it is provided that lost property will be valued based on the lesser of the:

"actual cash value of the property on the day the loss was discovered; cost to repair; or cost of replacing the property with material of like kind and quality, less allowance for physical deterioration, depreciation, obsolescence or depletion."

And, on page 5 of the policy under "Exclusions" is listed

"Consequential Loss - this insurance does not apply to the loss
of income, interest or dividends."

Thus, it seems clear, and plaintiff apparently concedes, that plaintiff's loss cannot properly be measured by the sum of money plaintiff would have been paid if the studies had all been valid and paid for per contract, or the sums

plaintiff has been obliged to refund to the pharmaceutical companies. Rather, plaintiff has characterized its claims as representing what it would have cost to replace the damaged studies. Plaintiff's evidence of replacement costs is, for the most part, based upon the amounts it actually did expend in conducting the original studies.

Defendant challenges some of the classes of expenditures included in these calculations but, in my view, plaintiff's figures represent a reasonable approximation of replacement costs, as contemplated by the policy.

Defendant advances another, somewhat metaphysical, argument: The value of lost property is supposed to be the lesser of the "actual cash value of the property on the day the loss was discovered" or replacement cost. In defendant's view, when the loss was discovered in April 1998, the studies were actually worthless or, at the very least, their actual value was much less than the cost of replacement. I reject this argument. In my view, the term "actual cash value of the property on the day the loss was discovered" means, in the circumstances of this case, the value of the property in its undamaged condition. I do not believe that the defendant, or any other insurance company, intended its policy to be illusory.

Having concluded that replacement cost is the appropriate measure of the loss sustained by plaintiff, I find it

unnecessary to assess the validity of any questionable items included in plaintiff's calculations because, under any view of the matter, the loss sustained (nearly two million dollars) greatly exceeded the policy limits, as determined in the following section.

IV. Policy Limits

As noted above, the policy provides, under "Limits of Insurance" (page 6):

"All losses resulting from an actual or attempted fraudulent or dishonest act or series of related acts at the premises... whether committed by one or more persons will be deemed to be one occurrence or event."

There can be no doubt that, as to all of the four studies in question, plaintiff's losses resulted from a "series of related acts": The same nurses were involved in all of the alleged wrongdoing, they acted in concert, and all of the alleged wrongful acts constituted a series of related acts. I reject plaintiff's argument that the policy is ambiguous and should be construed in favor of expanded coverage. I perceive no ambiguity.

I therefore conclude that, if plaintiff had succeeded in establishing coverage, the maximum amount of recovery in this action would have been \$280,000, the policy limit for a single loss.

V. Conclusion

For the reasons discussed above, I find that the defendant is not liable to the plaintiff. Judgment will be entered in favor of the defendant.

An Order follows.

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v.

FEDERAL INSURANCE COMPANY NO. 00-1129

<u>ORDER</u>

AND NOW, this day of November 2001, in accordance with the accompanying Adjudication, IT IS ORDERED:

Judgment is entered in favor of the defendant Federal Insurance Company and against the plaintiff.

John P. Fullam, Sr. J.